will be a busy period legislatively prior to the Memorial Day recess.

I think all Senators should be aware that bills are beginning to be reported out of committees. We have had 3 months to have the hearings to mark up legislation. We have a number of bills that have now been reported, including the TEAM Act and the Comptime and Flextime Act, which can be very helpful to families and working mothers who need time to be with their children. That legislation is ready. Sometime late this month or early next month we will, as I have said, have a vote on the partial-birth abortion ban legislation. So we are beginning now to enter a period where we will have a lot of legislation.

Obviously, we need to have a vote on the budget. I had hoped we could come to a grand agreement that would be in the best interests of all Americans with the President. So far, that has been fruitless. I have committed basically 3 months, along with the chairman of the Budget Committee, the time and the meetings, to try to see that something happened in this budget area, but we have not been successful with that. I had asked the President not to oppose the balanced budget constitutional amendment. He did. In fact, he and the leadership on the other side of the aisle twisted arms, and two Senators switched their positions, and we lost that by one vote. But every Republican and 11 Democrats had the courage of their convictions and voted for it.

Then I asked the President and his people to send us a real budget, a budget that showed courage, showed leadership, that would have some restraints in the entitlements area, that would preserve and protect Medicare, that would give some tax relief to working Americans, that would have some restraint and controls on the rate of increase on nondefense discretionary spending and would do what needs to be done in the defense area; show some leadership. They did not. They sent a political document.

Since that time, we have tried to encourage some movement with the suggestion that we have a commission to decide on the accurate, honest number of the Consumer Price Index. The President indicated preliminarily he thought maybe we could get a commission on that. To his credit, the Democratic leader indicated he thought that was a move in the right direction. But then they backed away from it. Other suggestions have been made by the Republican leadership, but there has been no reciprocation, no action.

The President needs to lead in this area. If he does not, we are moving on. We are moving on. We have to do this budget. We will do a budget in the Senate in the next few days. I think we have to get action in the Budget Committee here in the next couple of weeks. We have to get some decision made so the Appropriations Committee can begin to move forward. We hope it will be a bipartisan agreement. We would like to have the President's help, but the time is over for waiting. We must move forward. I will be talking later today to the chairman of the Budget Committee and interested Republicans and Democrats to see how we can proceed. We still would like to have the President's involvement and help, but he does not seem, so far, to be ready to do that.

Our staffs were meeting during the past 2 weeks. They were supposed to be making progress. From what I understand, they had a grand time meeting and saying how wonderful it was they were meeting—but that is about all. It was my understanding, from what the President said, that he would meet with the leadership of Congress when we returned from the Easter recess period to discuss, hopefully, the final decisions on the budget—this week. But I understand now, that meeting is not going to occur this week. It is next week. Yet, as we wait for leadership from the White House, we see some people saying, why doesn't the Congress act? We have been trying to confirm the President's Cabinet. We have been trying to work with the administration and to work off of his budget agreement so we could move to a final agreement. It has taken time. But that time is gone. We have to go ahead and do our job. And it will be our intent to do so.

So, I thank all Senators in advance for their cooperation as we begin what I hope will be a productive couple of months. We have a lot of good legislation we can take up, we will take up, and I think when we go out for the Memorial Day period we will have several bills that we can point to with pride that we have voted on.

UNANIMOUS-CONSENT AGREEMENT—S. 104

Mr. LOTT. Mr. President, I ask unanimous consent that at 1 p.m. today the Senate resume consideration of the motion to proceed to S. 104.

The PRESIDING OFFICER (Mr. ENZI). Without objection, it is so ordered.

MORNING BUSINESS

The PRESIDING OFFICER. Under the previous order, there will now be a period for morning business.

Mr. LOTT. Mr. President, seeing no Senator seeking recognition at this point, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. ASHCROFT. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. ASHCROFT. Mr. President, I ask unanimous consent that, for purposes of introducing a bill and making remarks in relation thereto, that I be granted permission to speak for up to 10 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. ASHCROFT. I thank the Chair.

(The remarks of Mr. ASHCROFT pertaining to the introduction of S. 514 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. ASHCROFT. Mr. President, I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Vermont.

FDA REFORM AND PDUFA REAUTHORIZATION

Mr. JEFFORDS. Mr. President, we are here today to talk about the need for us to reauthorize the Prescription Drug User Fee Act and pass legislation to modernize the Food and Drug Administration.

I will just remind everyone as to what happened last year. The Senate Labor Committee passed an FDA reform bill out of committee with a strong, bipartisan vote of 12–4.

So we are here today to alert the body that we intend to move forward expeditiously this year in order to ensure that we improve the FDA review process for new products as well as reauthorize the Prescription Drug User Fee Act. And we are going to do so in a bipartisan manner.

Let me state that I intend that these issues will move together. It is my goal, as chairman of the authorizing committee, to have a bill ready for the full Senate's consideration before midyear. During the last Congress, my predecessor, Senator Kassebaum, led our committee in reporting out legislation which emphasizes the FDA has a role in bringing needed products to the public in a timely fashion as well as a role of protecting the public from harm.

This year, I look forward to continuing that work. The objective of modernizing the FDA is to make more information and better products available to the public in an expeditious way, to foster and improve a new product review process, and require that the agency be as efficient and effective as possible in carrying out its statutorily defined duties.

As chairman of the Labor and Human Resources Committee, my approach will be to identify problem areas in the FDA regulatory system for drugs, devices, and other products which can be improved with legislation and gives the FDA the tools it needs to address other problems administratively.

Specifically, we will target areas that have the effect of needlessly delaying patient access to safe new therapies and products. In addition, we must not squander scarce FDA resources on bureaucratic procedures which confer no demonstrated public health benefit.

We must also reauthorize the successful Prescription Drug User Fee Act, also known as PDUFA.

In 1992, the pharmaceutical and biotechnological industries were so concerned about the length of time taken by FDA to approve new drugs that they were willing to adopt FDA's proposal that they pay user fees in exchange for faster reviews. FDA has been able to reduce mean approval times for new drugs to which user fees were paid from almost 30 months in 1992 to 15.5 months in 1996. We need to continue this effort.

Notwithstanding the success in reducing the review time for new drug applications, the period of time it takes pharmaceutical and biotechnological groups to work with FDA on the drug development phase before an application is even submitted has lengthened. It is my hope that we can introduce new performance measures for the FDA in addressing the drug development phase and further enhancing the drug review and approval phases as part of the reauthorization of PDUFA.

It is essential to note that these user fees are contingent on the Appropriations Committee's making available to the FDA the pre-1992 level of appropriated funds to the Agency updated for inflation. This provides the assurance that user fees do not become a substitute for funds appropriated from general revenues.

The administration's budget puts this important principle at risk with an 8-percent cut in the funding for the FDA. I know of Chairman STEVENS' interest in the FDA and its approval process. I look forward to working with him, the other Appropriations Committee, and the majority leader to make sure that the FDA has the full level of funding it needs to perform its vital functions across each of the centers.

Mr. President, the Labor and Human Resources Committee will move expeditiously to have the reauthorization of PDUFA and legislation to modernize the FDA ready for the consideration of the Senate.

Mr. President, I know the Senator from Maryland is here and also wants to join myself and the majority leader in making sure that the Senate does what it must do in order to make the improvements necessary to bring the FDA up to what it can be and should be.

Mr. President, I yield the floor.

Ms. MIKULSKI addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Maryland.

Ms. MIKULSKI. Mr. President, I want to state very clearly that I agree with the distinguished majority leader, the Republican leader, and the respected chairman of the Labor and Education Committee, Mr. JEFFORDS, in reauthorizing the Prescription Drug User Fee Act this year. And I also support strong bipartisan agreement on FDA reform. The time has come. The time is now. It is a window of opportunity to just do it.

I am so pleased that we are proceeding on this, and not only in a bipartisan fashion, but a nonpartisan fashion. I had the pleasure of working with the former chairman, Senator Nancy Kassebaum of Kansas, who retired, on fashioning a bipartisan framework on FDA reform.

I am so pleased that her successor, Senator JEFFORDS, has picked up the same framework as a working document for us to be able to proceed because this is what the American people want us to do—to work together to be able to have a Federal agency that oversees the approval of our pharmaceuticals, biotechnology, and biomedical devices to ensure their safety and efficacy, but also to make sure they move out into clinical practice in a timely way. This is what we need to do because it will save lives and generate jobs in the United States of America.

So I look forward to working with the distinguished chairman in fashioning the bill in committee and with the Republican leader in moving it to the Senate floor, because it is time to bring a smokestack regulatory framework into the computer age. FDA needs to adopt a new culture and move into the 21st century. That is why FDA reform is so important. We need a new regulatory framework that will make sure that we bring exciting new biomedical technology devices to not only millions of Americans in a timely fashion but this is a global field that will enable us to export around the world.

Our country has been often known for exporting smart weapons of war but this will enable us to export smart new technology in the war against disease. This will be absolutely crucial.

Reform is of great interest in my State of Maryland. Maryland is home to many biotechnology companies and medical device manufacturers and they are creating new scientific products which will save lives.

In the 104th Congress, under the able leadership of now retired Senator Kassebaum, we reached that bipartisan consensus on effective and responsible FDA reform. Then I was pleased to join several of my Democratic colleagues in supporting the Kassebaum bill. And I am committed to achieving meaningful bipartisan reform this year.

Coupled with FDA reform though, this is the year that we must reauthorize something called PDUFA. As has been outlined very ably by the chairman of the committee, this Prescription Drug User Fee Act has shown that it will significantly reduce drug approval time because it generated fees that have been used to hire more staff. It enabled the FDA to move more expeditiously in moving new drugs to patients more quickly. For example, new AIDS drugs are being approved now in a matter of months rather than a matter of years.

FDA itself is located in my own State. They work under very difficult situations. They work out of modular buildings, many of which are spread over 27 different sites. They often are short-staffed. And they need to make sure we pass PDUFA so that they have the adequate resources they need to do the job while we help them fashion an adequate legislative and regulatory framework.

We can build on this great track record. With the extension of PDUFA for another 5 years, we can have the opportunity to make further improvements. What can be done with some new drugs should be done for the benefit of many other patients.

Mr. President, we are talking about the need to provide all the help we can to a Government agency that has an enormous impact on the day-to-day lives of Americans. The FDA is involved with everything from the drugs we take to the food we eat. Let us move on PDUFA and FDA reform in a sensible, responsible bipartisan manner. And as this is done, we must focus on the values of safety and efficacy while we will also streamline our process.

I know also in the Chamber is the distinguished Senator from Oregon [Mr. WYDEN], who when we worked on the original PDUFA was in the House. He brings a great deal of knowledge to that. And we know he will be part of our bipartisan effort. So we thank you, I say to the Senator, and look forward to working with you.

In conclusion, I would like to also thank the chairman of the committee, Mr. JEFFORDS. He established a committee now called Public Health and Safety. It is the first time I believe in the committee's history that we have had a committee devoted strictly to focusing on the public health needs of the American people. The Centers for Disease Control and NIOSH and others will be so absolutely crucial. And being the gentleman that he is, he yielded that plum to another member of the committee, and enabled Dr. BILL FRIST to chair that committee, who brings to the committee the experience as a physician of a hands-on clinical practice as well as the know-how and what it really takes to be able to save lives.

This is what we need to be doing—the right committee structure, the right attitude within the committee so that we can all work together so that at the end of the term, we might not have solved every budget problem, we might not have balanced every line item, but at the end of this term people will be safer, their food, their pharmaceuticals, and so on, will be able to move quicker, faster, cheaper, maintaining safety and efficacy because of what this committee has done. I look forward to cooperating with that.

Mr. President, I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Vermont.

Mr. JEFFORDS. We are awaiting the arrival of the majority leader. I know the Senator from Oregon has somewhat

of a lengthy statement. I wonder if he would be willing to be interrupted by the majority leader should he arrive and that we also would place his statement preceding mine such that it would appear in the order originally intended.

Mr. WYDEN. I thank the gentleman for his courtesy. Perhaps we might wait a few more minutes for the leader.

Mr. JEFFORDS. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. LOTT. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. SESSIONS). Without objection, it is so ordered.

Mr. LOTT. Mr. President, this Congress has an opportunity to build on the progress made in the 104th Congress to assist the Food and Drug Administration in meeting the needs of millions of Americans who are awaiting the advancement of new medicines.

Over the years, I have known individuals who have needed medicines and medical procedures that they could not get because the FDA had not done whatever was necessary, in their opinion, to approve these procedures. I have known of examples of people going to Mexico for medicine or to England for a medical procedure because they could not get that procedure in America. Yet 20 years later, one of the procedures that Americans had to go to England to get now is so common it is almost done as an outpatient procedure. That is ridiculous, and it is time we make some progress in advancing these new medicines in a more expeditious manner.

We also have an urgent need to act to extend the highly successful law that will expire later this year unless it is renewed in a timely fashion.

Let me review last year's legislation that would enable the FDA to meet the demands of the rapidly approaching 21st century.

This past year, we had wide bipartisan agreement on essential elements of FDA reform in both Houses of Congress. In the Senate, the Labor and Human Resources Committee approved S. 1477, the Food and Drug Administration Performance and Accountability Act, by a 12-to-4 bipartisan margin. In the House, H.R. 3199, the Drug and Biological Products Reform Act was cosponsored by more than 200 Members of both parties.

It was unfortunate, Mr. President, that despite the best efforts of then Labor and Human Resources Chair Nancy Kassebaum, as well as my colleagues Senator DAN COATS and Senator CHRIS DODD, we ran out of time last year before S. 1477 could be brought to the Senate floor. I wanted to do it. They wanted to do it. A bipartisan group wanted to do it. In the face of a threatened filibuster by some Senators, we were not able to bring it to the floor with that threat hanging over the legislation.

However, as the urgency of this legislation becomes more and more apparent, I am confident that the Labor and Human Resources Committee under the able leadership of the distinguished Senator from Vermont [Mr. JEFFORDS], will undertake this worthy effort without delay.

Congress must also consider another important law this year, the 1992 Prescription Drug User Fee Act which is scheduled to expire on September 30, 1997.

The user fee law was the result of a historic agreement between Congress, the Food and Drug Administration, and the pharmaceutical and biotechnology industries. Industry agreed to pay $347 million in user fees during the 1993–97 period, which enabled the FDA to speed up the approval process by employing an additional 600 reviewers. Unless this vital law is renewed, the advances made by the FDA will be interrupted and the progress will be damaged.

As majority leader, I plan to do everything I can to ensure that PDUFA, the legislation I just referred to, is reauthorized for another 5 years, thus ensuring that our sickest patients will have fast access to life-saving products.

Mr. President, Congress must meet these two challenges. We must act now for the patients all across America. I certainly commend Senator JEFFORDS for his efforts in this area, his leadership, and my good friend, the Senator from Maryland, Senator MIKULSKI. She has been a leader in getting this colloquy and getting these statements printed in the RECORD today. I commend her and urge my colleagues on the appropriate committee and on both sides of the aisle to support these two very important pieces of legislation.

I yield the floor.

The PRESIDING OFFICER. The Senator from Oregon is recognized.

Mr. WYDEN. Mr. President, I ask unanimous consent to speak for 30 minutes as in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

MEDICARE

Mr. WYDEN. Mr. President, the process of making public policy, like much of life, is about opportunity, risk, and reward. That proposition is clearly demonstrated when the Senate looks at the critical issue of Medicare reform.

I take the floor today, as I plan to do every day this week, to talk about a tremendous opportunity that the Senate has before it, the opportunity to finally remake Medicare for the 21st century in a bipartisan way. The Senate ought to seize this opportunity to act now and act boldly so that Medicare can be preserved for future generations of Americans.

As Senators return from visiting their respective States today, we begin a legislative period that I believe can be a critical few months in Medicare's history. There is an opportunity to engage this issue as serious debate begins on the fiscal year 1998 budget. I believe that there is now a unique window of opportunity for reforming Medicare that would come along in only rare instances.

Three factors combine to make this a special opportunity to try to set Medicare on track for the next century. The first is that the Federal deficit is less than was anticipated for this year, just over $108 billion. Second, we have a fairly benign economy. Surely, there are too many folks still hurting, there are too many folks falling between the cracks, but overall the economy has been strong. Third, it is very clear that our country will face a demographic earthquake in the next century with so many more older people, and we have a window of opportunity now to act before those demographic trends are set in place.

My view is that Medicare does not need to be reformed because it has failed but because it has been such a great success that it cannot be allowed to deteriorate. I argue that only enemies of this program would want it to stay exactly as it is, because the status quo, the Medicare status quo that encourages waste and discourages user-friendly innovation, in my view, consigns Medicare to very difficult times.

The General Accounting Office, for example, has estimated that the gap between expected revenues for the program and the enormous service demands is going to produce a gap of almost a half trillion dollars at the end of the next decade. This program, which is a lifeline to 38 million senior citizens, faces very serious, if not calamitous, financial circumstances by the end of the decade. There are a variety of reasons for this, as I am going to outline this week.

In much of the United States, Medicare is engaging in wasteful practices that the private sector consigned to the attic years and years ago. In much of the country, Medicare is inefficient, volume-driven, clunky health care, and it is one of the first things that needs to be changed.

I believe that there are substantial opportunities for this Senate to move on Medicare reform, and I think there are some special areas that we should be careful to avoid. I say, Mr. President, and colleagues, that I think it would be a great mistake to appoint yet another bipartisan commission to study Medicare. A number of our colleagues have proposed that. I have great respect for them, but if there is another bipartisan committee that studies this issue, I believe we will see bipartisan inertia for Medicare for years and years to come. The first question a bipartisan commission would face is should they report before the 1998 election. Then there would be a question about whether they would report before the year 2000 election.

I do not think that a commission can create a forum for avoiding the tough